

U.S.S.N. 08/924,994

Filed: September 5, 1998

AMENDMENTS PURSUANT TO 37 C.F.R. § 1.121

Clean Version of Amended Claims

Sub D1
C1

1. (Twice Amended) A method for determining the level of an apolipoprotein in saliva comprising reacting the apolipoproteins in a saliva sample with antibodies immunoreactive with the apolipoprotein, using a quantitative assay kit comprising means for collection of saliva and antibodies immunoreactive with an apolipoprotein and means for comparing the levels of the apolipoproteins in the saliva with the levels in serum, detecting the amount of immunoreactivity between the antibodies and apolipoproteins in the saliva sample as determined by the quantitative assay, and comparing the amount of determined immunoreactivity with standards of known amounts of apolipoproteins reacted with the antibodies to determine the level of apolipoproteins in the saliva sample.

Sub D2

2. The method of claim 1 wherein the apolipoprotein is selected from the group consisting of Apo A, Apo B, Apo C, Apo E, and components thereof.

3. The method of claim 2 wherein the apolipoprotein is selected from the group consisting of Apo A1 and Apo B.

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4. (Amended) The method of claim 1 wherein the antibodies are labelled with a detectable label.

5. (amended) The method of claim 1 further comprising determining the level of apolipoprotein in the saliva sample within less than three hours following collection.

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6. (twice Amended) The method of claim 1 further comprising preparing the saliva in the sample by removing mucopolysaccharides from the saliva prior to determining the level of apolipoprotein in the saliva sample.

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7. (amended) The method of claim 1 further comprising collecting the saliva after stimulating its secretion from a subject.

8. The method of claim 1 further comprising determining the amount of albumin present in the saliva.

9. (twice Amended) The method of claim 8 further comprising correcting the determined amount of the apolipoprotein for the presence of albumin in the saliva sample.

10. (amended) The method of claim 1 further comprising collecting the saliva sample into a device which filters out mucopolysaccharides and comprises the antibodies immunoreactive with one or more of the apolipoproteins in the saliva sample.

11. The method of claim 10 wherein the apolipoprotein is either Apo A1 or Apo B.

12. An assay device or kit for determining the amount of apolipoprotein in a saliva sample comprising means for collection of saliva and antibodies immunoreactive with an apolipoprotein for use in a quantitative assay, and means for comparing the levels of the apolipoproteins in the saliva with the levels in serum.

13. (amended) The assay device or kit of claim 12 comprising filter means for removal of mucopolysaccharides from the saliva.

14. The assay device or kit of claim 12 wherein the antibodies are reactive with apolipoprotein selected from the group consisting of Apo A, Apo B, Apo C, Apo E, and components thereof.

15. The assay device or kit of claim 12 further comprising antibodies immunoreactive with albumin.

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16. (twice Amended) The assay device or kit of claim 12 wherein the antibodies immunoreactive with apolipoprotein in the saliva sample are immobilized on a solid support.

17. The assay device or kit of claim 16 comprising reagents for detection of complexes between the apolipoprotein and the antibodies.

18. (Amended) The assay device or kit of claim 12 comprising a strip or dipstick.

19. (Amended) The assay device or kit of claim 15 comprising as separate reagents antibodies to the apolipoprotein and antibodies to albumin.

20. (twice Amended) A method for quantitating the amount of lipoprotein or cholesterol in saliva or determining the presence of lipid disorders or risk of cardiovascular disease comprising

(a) reacting the apolipoproteins in a saliva sample with antibodies specifically immunoreactive with apolipoprotein selected from the group consisting of Apo A, Apo B, Apo C, Apo E, and components thereof in a quantitative assay,

(b) determining the amount of immunoreaction between the antibodies and the apolipoproteins in the saliva sample, and

(c) comparing the amount of immunoreaction determined in step b with the amount of immunoreaction of the antibodies immunoreactive with the apolipoprotein in the saliva sample with known quantities of apolipoprotein in normal or at risk individuals.

21. (amended) The method of claim 1 further comprising,

correlating the levels of HDL and/or LDL in the serum with the levels of apolipoproteins in serum,

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correlating the levels of the apolipoproteins in the serum based on the levels of apolipoproteins determined in the saliva sample, and extrapolating the levels of HDL and/or LDL in the serum, based on the levels of the apolipoproteins determined in the saliva sample.

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D11

22. (amended) The method of claim 20 comprising reacting the apolipoprotein in the saliva sample with antibodies specifically immunoreactive with an apolipoprotein selected from the group consisting of Apo A, Apo B, Apo C, Apo E, and components thereof, and correlating the levels of at least one apolipoprotein in the saliva with the levels of apolipoprotein in serum known to be correlated to the presence of lipid disorders or risk of cardiovascular disease.

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